9. 510(k) SUMMARY

9.1 Submitter's Name and Contact Information

Contact Person: Kevin G. Yost, PhD., Director, R&D
Phone: (773) 481-6898 Fax: (773) 777-6099
Email: kyost@jbutler.com

Submitter Company: John O. Butler Company
4635 W. Foster Ave.
Chicago, IL 60630

Date Prepared: August 30, 2002

9.2 Name of Device and Name/Address of Applicant

Butler GUM® Vari-Clean™ Power Toothbrush

John O. Butler Company
4635 W. Foster Ave.
Chicago, IL 60630

9.3 Common or Usual Name

Powered Toothbrushes with Antibacterial Bristles

9.4 Classification Name

Toothbrush, Powered

9.5 Predicate Device

The Butler GUM® Vari-Clean™ Power Toothbrush is substantially equivalent to the Medoral Hygienic Toothbrush marketed by Coronet Group North America described in K020776, 6/3/2002.

9.6 Intended Use

The Butler Powered toothbrush is intended for over-the-counter use as a toothbrush. The antibacterial agent impregnated in the filament kills bacteria and prevents their growth on and between the bristles after and between uses of the toothbrush.

9.7 Technological Characteristics and Substantial Equivalence

9.7.1 Technological Characteristics

The nylon bristles of the Butler GUM® Vari-Clean™ Toothbrush are impregnated with silver, which provides long-lasting antibacterial protection of the bristles.

9.7.2 Substantial Equivalence

The nylon bristles of the Butler GUM® Vari-Clean™ Power Toothbrush are identical to the bristles cleared by FDA in K020776, which is the predicate for this 510(k). There is no reason to believe that any new questions of safety and efficacy are raised by the use of the identical bristles in Butler GUM® Vari-Clean™ Power Toothbrushes and the two devices should be deemed substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2002

Dr. Kevin G. Yost
Director of R & D
John O. Butler Company
4635 West Foster Avenue
Chicago, Illinois 60630

Re: K022900
Trade/Device Name: Butler GUM® Vari-Clean™ Power Toothbrush
Regulation Number: 21 CFR 872.6865
Regulation Name: Powered Toothbrushes
Regulatory Class: I
Product Code: JEQ
Dated: August 30, 2002
Received: September 3, 2002

Dear Dr. Yost:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K022900

Applicant: John O. Butler Company
4635 W. Foster Avenue
Chicago, IL 60630
voice: 773.481.6898 fax: 773.777.6099

Device Name: Powered Toothbrushes with Antibacterial Bristles

Proprietary Name: Butler GUM® Vari-Clean™ Power Toothbrush

Indications For Use:

Butler's Antibacterial Power Toothbrushes are devices that include a handle to be held in the hand and bristles (filaments) at one end to remove adherent plaque and food debris from the teeth to reduce tooth decay. The antibacterial agent impregnated in the filament kills bacteria and prevents their growth on and between the bristles between uses.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number K022900

Prescription Use _____ OR Over-The-Counter Use ✓

(Optional Format 1-2-96)